

Melissa A. Chuderewicz
PEPPER HAMILTON LLP
(A Pennsylvania Limited Liability Partnership)
301 Carnegie Center
Suite 400
Princeton, NJ 08543-5276
Tel: (609) 951-4118
Fax: (609) 452-1147
chuderem@pepperlaw.com

Attorneys for Plaintiffs
Dow Pharmaceutical Sciences, Inc.
and Valeant Pharmaceuticals North America LLC

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

DOW PHARMACEUTICAL SCIENCES, INC.
and VALEANT PHARMACEUTICALS
NORTH AMERICA LLC,

Plaintiffs,

v.

TARO PHARMACEUTICALS U.S.A., INC.
and TARO PHARMACEUTICAL
INDUSTRIES LTD.,

Defendants.

Civil Action No.: _____

Document Electronically Filed

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Dow Pharmaceutical Sciences, Inc. (“Dow”) and Valeant Pharmaceuticals North America LLC (“Valeant”) (collectively, “Plaintiffs”) by way of Complaint against Defendants Taro Pharmaceuticals U.S.A., Inc. (“Taro USA”) and Taro Pharmaceutical Industries Ltd. (“Taro Industries”) (collectively, “Taro” or “Defendants”) allege as follows:

THE PARTIES

1. Plaintiff Dow is a corporation organized and existing under the laws of California

having its principal place of business at 1330 Redwood Way, Petaluma, California 94954.

2. Plaintiff Valeant is a limited liability company organized and existing under the laws of Delaware having its principal place of business at 400 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807.

3. Upon information and belief, Taro USA is a New York corporation with places of business at Three Skyline Drive, Hawthorne, New York 10532, and One Commerce Drive, Cranbury, New Jersey 08512.

4. Upon information and belief, Taro Industries is an Israeli corporation with a place of business at 14 Hakitor Street, Haifa Bay, 2624761, Israel.

5. Upon information and belief, defendant Taro USA is a wholly-owned subsidiary of defendant Taro Industries and acts at the direction of, under the control of, and for the benefit of Taro Industries.

NATURE OF THE ACTION

6. This is an action for infringement of United States Patent No. 8,288,434 (“the ’434 patent”) arising under the United States patent laws, Title 35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281. This action relates to Taro’s filing of an Abbreviated New Drug Application (“ANDA”) under section 505(j) of the Federal Food, Drug, and Cosmetic Act (“the Act”), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration (“FDA”) approval to market its generic benzoyl peroxide and clindamycin phosphate topical gel (3.75%; Eq. 1.2% Base) (“Taro’s generic benzoyl peroxide and clindamycin phosphate topical gel”).

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

8. Upon information and belief, this Court has jurisdiction over Taro USA. Upon

information and belief, Taro USA is in the business of manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products manufactured by Taro Industries. Upon information and belief, Taro USA directly, or indirectly, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Taro's generic benzoyl peroxide and clindamycin phosphate topical gel. Upon information and belief, Taro USA purposefully has conducted and continues to conduct business in this judicial district.

9. Upon information and belief, Taro USA is registered to do business in New Jersey under business ID 0100917783, is registered as a wholesale drug distributor under registration number 5003062, and has appointed the Corporation Trust Company, 820 Bear Tavern Road, West Trenton, NJ 08628 as its registered agent for service of process.

10. Upon information and belief, Taro USA owns a drug distribution facility in South Brunswick, New Jersey having an address of 1 Commerce Dr., Cranbury, NJ 08512.

11. Upon information and belief, this court has jurisdiction over Taro Industries. Upon information and belief, Taro Industries is in the business of manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Taro Industries directly, or indirectly, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Taro's generic benzoyl peroxide and clindamycin phosphate topical gel. Upon information and belief, Taro Industries purposefully has conducted and continues to conduct business in this judicial district.

12. Taro Industries has reported to the United States Securities and Exchange Commission that it "operates through three entities," including Taro USA, and has reported that

it owns two “principle facilities” in the United States, including a distribution facility in South Brunswick, New Jersey.

13. Taro USA has availed itself of the rights, benefits, and privileges of this Court by filing at least two complaints for patent infringement in the District of New Jersey: *Taro Pharmaceuticals North America, Inc. et al. v. Suven Life Sciences, Ltd.*, Civil Action No. 3:11-cv-02452 and *Taro Pharmaceuticals North America, Inc. et al. v. Synerx Pharma, LLC*, Civil Action No. 2:09-cv-03569.

14. Taro USA and Taro Industries have admitted to, consented to, or have not contested the jurisdiction of this Court in at least three prior District of New Jersey actions: *Novartis Pharmaceuticals Corporation et al. v. Taro Pharmaceuticals USA, Inc. et al.*, Civil Action No. 2:06-cv-04178; *Medicis Pharmaceutical Corporation v. Taro Pharmaceuticals USA, Inc. et al.*, Civil Action No. 1:15-cv-02841; and *Horizon Pharma Ireland Limited et al. v. Taro Pharmaceuticals USA, Inc. et al.*, Civil Action No. 1:15-cv-02046.

15. Taro USA and Taro Industries have availed themselves of the rights, benefits, and privileges of this Court by asserting counterclaims in at least three prior District of New Jersey actions: *Pfizer, Inc. v. Taro Pharmaceuticals Industries, Ltd. et al.*, Civil Action No. 2:03-cv-05425, *Novartis Pharmaceuticals Corporation et al. v. Taro Pharmaceuticals USA, Inc. et al.*, Civil Action No. 2:06-cv-04178 and *Schering Corp. v. Taro Pharmaceuticals USA, Inc.*, Civil Action No. 2:01-cv-03531.

16. Taro knows or should know that Onexton® is manufactured for Valeant Pharmaceuticals North America LLC in Bridgewater, NJ 08807 USA at least because that information is included in Onexton®’s label and prescribing information.

17. Upon information and belief, venue is proper in this judicial district under 28

U.S.C. §§ 1391(c) and (d), and § 1400(b).

THE PATENT IN SUIT

18. The U.S. Patent and Trademark Office (“PTO”) issued the ’434 patent on October 16, 2012. The ’434 patent claims, *inter alia*, formulations of benzoyl peroxide, including formulations of benzoyl peroxide and clindamycin, and methods of treating acne with such formulations. Plaintiffs hold all substantial rights in the ’434 patent and have the right to sue for infringement thereof. A copy of the ’434 patent is attached hereto as Exhibit A.

19. Dow is the holder of New Drug Application (“NDA”) No. 050819 for Onexton[®], which the FDA approved on November 24, 2014. In conjunction with NDA No. 050819, the ’434 patent is listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”).

20. Benzyl peroxide and clindamycin phosphate topical gel (3.75%; Eq. 1.2% Base) is sold in the United States under the trademark Onexton[®].

TARO’S INFRINGING ANDA SUBMISSION

21. Upon information and belief, Taro filed or caused to be filed with the FDA ANDA No. 208683, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

22. Upon information and belief, Taro’s ANDA No. 208683 seeks FDA approval to sell in the United States Taro’s generic benzoyl peroxide and clindamycin phosphate topical gel, intended to be a generic version of Onexton[®].

23. Dow received a letter from Taro USA and Taro Industries sent on December 1, 2015, purporting to be a Notice of Certification for ANDA No. 208683 (“Taro’s notice letter”) under Section 505(j)(2)(B)(ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(ii), and 21 § C.F.R. 314.95(c). Taro’s notice letter refers to both entities collectively as “Taro.”

24. Taro's notice letter alleges that Taro has submitted to the FDA ANDA No. 208683 seeking FDA approval to sell Taro's generic benzoyl peroxide and clindamycin phosphate topical gel, intended to be a generic version of Onexton[®].

25. Taro's notice letter, which is required by statute and regulation to provide a full and detailed explanation regarding any non-infringement defenses, does not allege non-infringement of claims 1, 4-9, 12-19, 22-27, 30-36, 41, 44-49, and 52-58 of the '434 patent.

26. Upon information and belief, ANDA No. 208683 seeks approval of Taro's generic benzoyl peroxide and clindamycin phosphate topical gel that is the same, or substantially the same, as Onexton[®].

27. Upon information and belief, Taro USA's actions relating to ANDA No. 208683 complained of herein were done with the cooperation, the participation, the assistance of, and at least in part for the benefit of Taro Industries.

COUNT I AGAINST TARO

Infringement of the '434 Patent under § 271(e)(2)

28. Paragraphs 1-27 are incorporated herein as set forth above.

29. Under 35 U.S.C. § 271(e)(2), Taro has infringed at least one claim of the '434 patent by submitting, or causing to be submitted to the FDA, ANDA No. 208683 seeking approval for the commercial marketing of Taro's generic benzoyl peroxide and clindamycin phosphate topical gel before the expiration date of the '434 patent.

30. Upon information and belief, Taro's generic benzoyl peroxide and clindamycin phosphate topical gel will, if approved and marketed, infringe at least one claim of the '434 patent.

31. Upon information and belief, Taro will, through the manufacture, use, import,

offer for sale, and/or sale of Taro's generic benzoyl peroxide and clindamycin phosphate topical gel, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '434 patent.

COUNT II AGAINST TARO

Declaratory Judgment of Infringement of the '434 Patent

32. Paragraphs 1-31 are incorporated herein as set forth above.

33. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

34. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

35. Taro has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Taro's generic benzoyl peroxide and clindamycin phosphate topical gel before the expiration date of the '434 patent, including Taro's filing of ANDA No. 208683.

36. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Taro's generic benzoyl peroxide and clindamycin phosphate topical gel will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '434 patent.

37. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Taro's generic benzoyl peroxide and clindamycin phosphate topical gel will constitute infringement of at least one claim of the '434 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment in their favor and against Taro on the patent infringement claims set forth above and respectfully request that this Court:

1. enter judgment that, under 35 U.S.C. § 271(e)(2), Taro has infringed at least one claim of the '434 patent by submitting or causing to be submitted ANDA No. 208683 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Taro's generic benzoyl peroxide and clindamycin phosphate topical gel before the expiration of the '434 patent;
2. order that the effective date of any approval by the FDA of Taro's generic benzoyl peroxide and clindamycin phosphate topical gel be a date that is not earlier than the expiration of the '434 patent, or such later date as the Court may determine;
3. enjoin Taro from the commercial manufacture, use, import, offer for sale, and/or sale of Taro's generic benzoyl peroxide and clindamycin phosphate topical gel until expiration of the '434 patent, or such later date as the Court may determine;
4. enjoin Taro and all persons acting in concert with Taro from seeking, obtaining, or maintaining approval of Taro's ANDA No. 208683 until expiration of the '434 patent;
5. declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs costs, expenses, and disbursements in this action, including reasonable attorney's fees;
6. award Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: January 12, 2016

Respectfully submitted,

s/ Melissa A. Chuderewicz

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PEPPER HAMILTON LLP

(A Pennsylvania Limited Liability Partnership)

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Suite 400

Princeton, NJ 08543-5276

(609) 951-4118

chuderem@pepperlaw.com

Attorneys for Plaintiffs

Dow Pharmaceutical Sciences, Inc., and

Valeant Pharmaceuticals North America LLC

Of Counsel:

Bryan C. Diner

Justin J. Hasford

M. Andrew Holtman

FINNEGAN, HENDERSON,

FARABOW, GARRETT & DUNNER, LLP

901 New York Avenue, NW

Washington, DC 20001-4413

(202) 408-4000

CERTIFICATION OF NON-ARBITRABILITY
PURSUANT TO LOCAL CIVIL RULE 201.1(d)

Pursuant to Local Civil Rule 201.1(d), the undersigned counsel hereby certifies that this action seeks declaratory and injunctive relief and, therefore, is not subject to mandatory arbitration.

I hereby certify that the foregoing statements made by me are true. I am aware that if any of the statements made by me are willfully false, I am subject to punishment.

s/ Melissa A. Chuderewicz

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Attorneys for Plaintiffs

DOW PHARMACEUTICAL SCIENCES, INC., and

VALEANT PHARMACEUTICALS NORTH

AMERICA LLC

Dated: January 12, 2016